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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,243	12/21/2000	Narendra Parikh	JBP514	8350

7590 07/15/2002
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EXAMINER

PULLIAM, AMY E

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/15/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/745,243	Applicant(s) PARIKH ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- Th MAILING DATE of this communication app ars on th cover sh et with th correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,8</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the Election of Species and the Information Disclosure Statement, received by the Office April 26, 2002, and April 29, 2002, respectively.

Election/Restrictions

Applicant's election with traverse of Group 1, claims 1-26 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the claims include sufficiently few species such that a search and examination of all the species at one time would not impose a serious burden on the examiner. This is not found persuasive because the species are different and distinct, and would cause a burdensome search on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statements have been acknowledged, signed and are returned with this office action. The sole exception is the citation to USSN 60/215,505, which is the citation to a provisional application. This application can not be used as prior art, and therefore has not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2053721 (JP '721), in view of Us Patent 4,309,405 to Guly *et al.*, and further in view of either US Patent 5,711,961 to Reiner *et al.* OR US Patent 5,098,715 to McCabe *et al.*.

JP '721 teaches tablets obtainable by compressing a pharmaceutical composition containing coated granules, wherein the coated granules are coated with one or more of an insoluble polymer, enteric polymer, or waxes, and these coated granules are further coated with a water soluble polymer or acid soluble polymer. More specifically, the water soluble polymer can be hydroxypropylmethyl cellulose, polyvinylpyrrolidone, polyethylene glycol, or gelatin.

The abstract of JP '721 does not specifically teach specific examples of the enteric and insoluble polymers used in the first coating layer.

Guley *et al.* teaches sustained release pharmaceutical compositions. However, the Guley *et al.* reference is relied upon for the teaching of specific insoluble and enteric coating polymers. Guley *et al.* teaches that ethylcellulose is a well known insoluble polymer used in pharmaceutical compositions (c 2, l 45-49). Additionally, Guley *et al.* teaches that well known enteric coating materials include cellulose acetate phthalate, and HPMC phthalate (c 3, l 15-20).

It is the position of the examiner that one of ordinary skill in the art would have been motivated to look to teachings in the art to provide examples of well known insoluble polymers and enteric coating polymers. Furthermore, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use any of the insoluble polymers discussed by Guley, and any of the enteric polymers disclosed by Guley, in the first coating layer disclosed by JP '721, because JP '721 requires the specific types of coatings, but does not give specific

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examples. The expected result would be a successful tablet composition, as disclosed by JP '721.

Additionally, the combination of JP '721 and Guley *et al.* do not teach the presence of PEG in the outer layer.

McCabe *et al.* disclose a thin film coating on solid oral dosage pharmaceutical tablets containing unpleasant tasting ingredients. More specifically, McCabe *et al.* are relied upon for the teaching that HPMC in combination with polyethylene glycol as a plasticizer, is well known in external coatings in the pharmaceutical art (c 4, l 44-47).

Reiner *et al.* disclose chewing gum tablets. More specifically, Reiner *et al.* teach that their gum tablets are spraylacquered with the use of lacquers usually comprising HPMC and PEG (c 2, l 45-50).

Each of these references shows that it is known in the pharmaceutical art to add plasticizers to polymeric coatings. Furthermore, both references show that HPMC and PEG are known in combination to be successful. Therefore, it is the position of the examiner that one of ordinary skill in the art would have been motivated to add a well known plasticizer, such as PEG, to the second coating layer (made of HPMC) in the formulation of JP '721. The expected result would be a glossier and more lacquered finish. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep
July 11, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600